

### General

#### Guideline Title

ACR Appropriateness Criteria® suspected osteomyelitis of the foot in patients with diabetes mellitus.

### Bibliographic Source(s)

Kransdorf MJ, Weissman BN, Appel M, Bancroft LW, Bennett DL, Bruno MA, Fries IB, Hayes CW, Holly L, Jacobson JA, Luchs JS, Morrison WB, Mosher TJ, Murphey MD, Palestro CJ, Roberts CC, Rubin DA, Stoller DW, Tuite MJ, Ward RJ, Wise JN, Zoga AC, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® suspected osteomyelitis of the foot in patients with diabetes mellitus. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [34 references]

#### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: Schweitzer ME, Daffner RH, Weissman BN, Bennett DL, Blebea JS, Jacobson JA, Morrison WB, Resnik CS, Roberts CC, Rubin DA, Seeger LL, Taljanovic M, Wise JN, Payne WK, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® suspected osteomyelitis in patients with diabetes mellitus. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 7 p. [22 references]

## Recommendations

### Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Suspected Osteomyelitis of the Foot in Patients with Diabetes Mellitus

<u>Variant 1</u>: Soft-tissue swelling without neuropathic arthropathy or ulcer.

| Radiologic Procedure   | Rating | Comments  | RRL*                            |
|--|--------|---|---------------------------------|
| X-ray foot   | 9      | Initial study. Radiographs and MRI are complementary and both are indicated. The results of initial x-ray examination do not preclude the necessity for additional studies.                         | €                               |
| REPUTÉ CONTROL 200 de la propriete de la control de la con |        | are indicated. MRI is useful preoperatively to identify the extent of involvement and to map devitalized areas.  See statement regarding contrast in the text below under "Anticipated Exceptions." | *Retative<br>Radiation<br>Level |

| MRI foo <b>Radiologic Procedure</b>   | Rating                   | Radiographs and MR Carron Sementary and both  | RRL*                            |
|---|--------------------------|---|---------------------------------|
|   |                          | are indicated.  |                                 |
| Labeled leukocyte scan foot (In-111 or Tc-99m)  | 3                        | May be appropriate in certain circumstances such as if MRI is contraindicated or unavailable. | ***                             |
| Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot                                       | 1                        |   | ***                             |
| Tc-99m 3-phase bone scan foot   | 1                        |   | \$ \$ \$                        |
| Labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot                              | 1                        |   | ***                             |
| Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot | 1                        |   | ***                             |
| US foot   | 1                        |   | О                               |
| CT foot without contrast  | 1                        |   | €                               |
| CT foot without and with contrast   | 1                        |   | ⊗                               |
| CT foot with contrast   | 1                        |   | €                               |
| FDG-PET/CT foot   | 1                        |   | ***                             |
| Rating Scale: 1,2,3 Usually not appropri  | iate; 4,5,6 May be appro | opriate; 7,8,9 Usually appropriate  | *Relative<br>Radiation<br>Level |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 2</u>: Soft-tissue swelling with neuropathic arthropathy without ulcer.

| Radiologic Procedure  | Rating             | Comments  | RRL*                  |
|---|--------------------|---|-----------------------|
| X-ray foot  | 9                  | Initial study. Radiographs and MRI are complementary and both are indicated. The results of initial x-ray examination do not preclude the necessity for additional studies.   | €                     |
| MRI foot without and with contrast  | 9                  | Radiographs and MRI are complementary and both are indicated. MRI is useful preoperatively to identify the extent of involvement and to map devitalized areas. See statement regarding contrast in the text below under "Anticipated Exceptions." | O                     |
| MRI foot without contrast   | 9                  | Radiographs and MRI are complementary and both are indicated.   | О                     |
| CT foot without contrast  | 5                  | For neuropathy or if MRI contraindicated.   | ₩                     |
| Labeled leukocyte scan foot (In-111 or Tc-99m)  | 3                  | May be appropriate in certain circumstances such as if MRI is contraindicated or unavailable.   | ***                   |
| Labeled leukocyte scan (In-111 or Tc-<br>99m) and Tc-99m sulfur colloid marrow<br>scan foot | 3                  | May be appropriate in selected clinical circumstances.  | ***                   |
| CT foot without and with contrast   | 1                  |   | <b>☆</b>              |
| CT foot with contrast   | 1                  |   | €                     |
| Tc-99m 3-phase bone scan foot   | 1                  |   | <b>⊛</b> ⊛⊛           |
| Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot                 | 1                  |   | ***                   |
| Rating Sieple is t, B, 3nd Soudly midtappetopriat   | e; 4,5,6 May be ap | propriate; 7,8,9 Usually appropriate  | Relative<br>Radiation |

| leukocyte schold bid blor Trag9m) and<br>Te-99m sulfur colloid marrow scan foot<br>US foot | Rating                      | Comments                          | RRL*                            |
|--|-----------------------------|-----------------------------------|---------------------------------|
| US foot  | 1                           |                                   | О                               |
| FDG-PET/CT foot  | 1                           |                                   | ***                             |
| Rating Scale: 1,2,3 Usually not approp   | priate; 4,5,6 May be approp | oriate; 7,8,9 Usually appropriate | *Relative<br>Radiation<br>Level |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 3</u>: Soft-tissue swelling without neuropathic arthropathy with ulcer.

| Radiologic Procedure  | Rating               | Comments   | RRL*                            |
|---|----------------------|--|---------------------------------|
| X-ray foot  | 9                    | Initial study. Radiographs and MRI are complementary, and both are indicated. The results of initial x-ray examination do not preclude the necessity for additional studies.   | ₩                               |
| MRI foot without and with contrast  | 9                    | Radiographs and MRI are complementary, and both are indicated. MRI is useful preoperatively to identify the extent of involvement and to map devitalized areas. See statement regarding contrast in text under "Anticipated Exceptions." | О                               |
| MRI foot without contrast   | 9                    | Radiographs and MRI are complementary and both are indicated.  | О                               |
| Labeled leukocyte scan foot (In-111 or Tc-99m)  | 3                    | May be appropriate in certain circumstances such as if MRI is contraindicated or unavailable.  | ***                             |
| Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot                                       | 1                    |  | ***                             |
| Tc-99m 3-phase bone scan foot   | 1                    |  | ₩₩                              |
| Labeled leukocyte scan (In-111 or Tc-<br>99m) and Tc-99m sulfur colloid marrow<br>scan foot                       | 1                    |  | ***                             |
| Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot | 1                    |  | 8888                            |
| US foot   | 1                    |  | О                               |
| CT foot without contrast  | 1                    |  | €                               |
| CT foot without and with contrast   | 1                    |  | <b>☆</b>                        |
| CT foot with contrast   | 1                    |  | ⊗                               |
| FDG-PET/CT foot   | 1                    |  | ***                             |
| Rating Scale: 1,2,3 Usually not appropriate   | te; 4,5,6 May be app | propriate; 7,8,9 Usually appropriate   | *Relative<br>Radiation<br>Level |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

<u>Variant 4</u>: Soft-tissue swelling with neuropathic arthropathy and ulcer.

| Radiologic Procedure                  | Rating                      | Comments   | RRL*                            |
|---------------------------------------|-----------------------------|--|---------------------------------|
| Rating@tale: 1,2,3 Usually not approp | priate; 4,5,6 May be approp | oriantia,1748,69/I.RazidigraphropriaNtRI are complementary, and both are indicated. The results of initial x-ray examination do not preclude the necessity | *Relative<br>Radiation<br>Level |

| MRI foor without and with contrast  | Rating                  | for additional studies. Comments Radiographs and MR are complementary, and both | RRL*                            |
|---|-------------------------|---|---------------------------------|
|   |                         | are indicated. MRI is useful preoperatively to identify                         |                                 |
|   |                         | the extent of involvement and to map devitalized areas.                         |                                 |
|   |                         | See statement regarding contrast in text under "Anticipated Exceptions."        |                                 |
|   |                         | 1 1   |                                 |
| MRI foot without contrast   | 9                       | Radiographs and MRI are complementary and. both are indicated.                  | О                               |
| Labeled leukocyte scan (In-111 or Tc-<br>99m) and Tc-99m sulfur colloid marrow<br>scan foot                       | 3                       |   | ***                             |
| Labeled leukocyte scan foot (In-111 or Tc-99m)  | 1                       |   | ***                             |
| Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) foot                                       | 1                       |   | ***                             |
| Tc-99m 3-phase bone scan foot   | 1                       |   | ₩₩₩                             |
| Tc-99m 3-phase bone scan and labeled leukocyte scan (In-111 or Tc-99m) and Tc-99m sulfur colloid marrow scan foot | 1                       |   | ***                             |
| CT foot without contrast  | 1                       |   | €                               |
| CT foot without and with contrast   | 1                       |   | €                               |
| CT foot with contrast   | 1                       |   | ₩                               |
| US foot   | 1                       |   | 0                               |
| FDG-PET/CT foot   | 1                       |   | ***                             |
| Rating Scale: 1,2,3 Usually not appropr   | iate; 4,5,6 May be appr | opriate; 7,8,9 Usually appropriate  | *Relative<br>Radiation<br>Level |

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

#### Summary of Literature Review

#### Introduction/Background

Throughout the last 50 years there has been much written about the diabetic foot, with little consensus as to whether, when, and what imaging is appropriate. This overview summarizes the literature and makes recommendations for imaging based on the available data. It is important to emphasize that in diabetics, virtually all foot osteomyelitis is due to direct spread from an adjacent soft-tissue infection, not from hematogenous seeding. Accordingly, this review discusses several clinical situations in which osteomyelitis or diabetic pedal disease is suspected but clinical findings differ because of the presence or absence of soft-tissue swelling, ulceration, and neuropathy.

Note that although several of the variants have similar recommendations, they present as unique clinical scenarios.

#### Soft-Tissue Swelling without Neuropathic Arthropathy or Ulcer

The probability of having osteomyelitis in a diabetic foot without evidence of ulceration of the adjacent soft tissue is extremely low. Whether there is or is not soft-tissue swelling, these patients have almost no incidence of osteomyelitis and a low incidence of septic arthritis, but some frequency of soft-tissue infections. The only situation in which such a patient can have osteomyelitis is the presence of a "hidden" ulcer that has granulated over and may appear healed. In that situation the risk of osteomyelitis is still extremely low, since the ulcer would not have granulated over if osteomyelitis were present. Therefore, without a clinically apparent ulcer, the role of imaging may be to diagnose neuropathic disease or to confirm the presence of soft-tissue infection, establish its extent, and identify any associated complications (e.g., abscess, foreign matter).

#### Soft-Tissue Swelling with Neuropathic Arthropathy without Ulcer

A more difficult question is whether soft-tissue swelling is the result of neuropathic arthropathy or soft-tissue infection (with or without osteomyelitis). In a patient who has neuropathic arthropathy, the risk of infection is usually low if there is no ulceration. Radiography can be used as a screening examination; however, computed tomography (CT) can identify neuropathic arthropathy that may be radiographically occult and may

be the cause of the swelling and pain (mimicking infection). CT cannot reliably exclude osteomyelitis. The use of positron emission tomography with CT (PET/CT) for diagnosing diabetic pedal osteomyelitis has been studied, but the data are limited and contradictory, and its role is currently uncertain.

Bone scintigraphy is indeterminate in the diagnosis of osteomyelitis; however, a negative bone scan excludes infection with a high degree of certainty. Indium white blood cell (WBC) scintigraphy, in general, is more accurate. A negative indium WBC study strongly supports the absence of infection. Since labeled leukocytes accumulate in the uninfected neuropathic joint, performing complementary technetium-99m sulfur colloid bone marrow imaging facilitates the differentiation of labeled leukocyte uptake due to bone marrow from that due to infection. Magnetic resonance imaging (MRI) generally has the best clinical results in this scenario with or without contrast, but the yield is going to be low in this group of patients.

The early diagnosis of neuropathic disease prior to the development of radiographic change is important, as these patients will be treated with altered footwear and orthotics to prevent the progression to deformity. Scintigraphy is, however, extremely sensitive to early neuropathic disease, long before radiographic changes are present. MRI is less sensitive but is a better test if there is a possibility of soft-tissue infection. A report noted increased low-level hypermetabolic activity on PET/CT in neuropathic arthropathy, easily distinguishing it from the normal foot and the infected neuropathic arthropathy, although other reports note PET/CT as indeterminate.

#### Soft-Tissue Swelling with Ulcer Extending to Bone

If an ulcer is present, the risk of infection is high (12%-20%). If the bone is exposed or if the ulcer extends to bone (positive probe-to-bone test), the likelihood of osteomyelitis is even greater (20%-66%), though how much greater depends on the pretest probability in the population studied. In general, a positive probe-to-bone test is of moderate predictive value. A negative test, however, may exclude the diagnosis of osteomyelitis with a high negative predictive value. The role of imaging in these patients is to confirm the presence of infection and show its extent. Radiographic features will vary with the virulence and extent of the infection, but generally will not become positive for several days to weeks following infection. While a negative bone scan excludes osteomyelitis, a positive study is quite nonspecific. Surprisingly, indium-labeled WBC scan, even when combined with sulfur colloid marrow imaging, has low specificity, although if the ulcer is away from the joint, these techniques are better. MRI has high specificity and sensitivity both with and without contrast, although intravenous contrast is especially useful to identify associated complications. Ultrasound (US) may have promise in long bones but, to date, data about its utility in diagnosing the diabetic foot are quite limited. The role of fluorine-18-2- fluoro-2-deoxy-D-glucose (FDG)-PET is still evolving, and comparisons of its value in diagnosing osteomyelitis with that of MRI have yielded conflicting results.

#### Neuropathic Arthropathy with Ulcer Extending to Bone

In patients who have diabetes and secondary neuropathic arthropathy, the infection is usually over an osseous abnormality with an ulcer. If the ulcer tracks down to bone, the risk of osteomyelitis is high, perhaps even higher than in the preceding situation where there is an ulcer without neuropathic arthropathy. The overall role of imaging therefore, is more to determine the extent of the disease than to definitively diagnose it. Most authors do not advocate scintigraphy in this situation because of its relatively poor spatial resolution for extent of disease; similar conclusions apply to PET.

Indium-labeled WBC scanning with bone marrow scanning accurately diagnoses osteomyelitis in the neuropathic foot but is poor at showing the anatomic extent of infection. Radiography has a high specificity but low sensitivity. US is unproven. CT will show the neuropathic arthropathy disease but not much else. MRI should be performed to determine extent of disease. Intravenous contrast is especially useful to identify associated complications, such as complex fluid collections, abscesses, or nonvascularized tissue, information that is also important for surgical planning.

#### Summary

- If a patient has an ulcer that extends to bone, osteomyelitis is quite likely but not invariably present.
- If there is no ulcer and there is still a clinical suspicion of infection, MRI is the test of choice.
- Conventional radiographs should be done simultaneously in both situations.
- When imaging is indeterminate, aspiration/biopsy should be considered.

#### Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible

benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m<sup>2</sup>. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

#### Abbreviations

- CT, computed tomography
- FDG-PET, fluorine-18-2-fluoro-2-deoxy-D-glucose-positron emission tomography
- In, indium
- MRI, magnetic resonance imaging
- Tc, technetium
- US, ultrasound

Relative Radiation Level Designations

| Relative Radiation Level* | Adult Effective Dose Estimate Range | Pediatric Effective Dose Estimate Range |
|---------------------------|-------------------------------------|---|
| O                         | 0 mSv                               | 0 mSv                                   |
| ₩                         | <0.1 mSv                            | <0.03 mSv                               |
| ₩ ₩                       | 0.1-1 mSv                           | 0.03-0.3 mSv                            |
| <b>⊛</b> ⊛                | 1-10 mSv                            | 0.3-3 mSv                               |
| ♥♥♥♥                      | 10-30 mSv                           | 3-10 mSv                                |
| ***                       | 30-100 mSv                          | 10-30 mSv                               |

<sup>\*</sup>RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."

### Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

# Scope

# Disease/Condition(s)

- Diabetes mellitus
- Osteomyelitis (diabetic pedal disease)

# Guideline Category

Diagnosis

Evaluation

Risk Assessment

## Clinical Specialty

Endocrinology

Family Practice

| Nuclear Medicine   |
|--------------------|
| Orthopedic Surgery |

Internal Medicine

#### **Intended Users**

Health Plans

Radiology

Hospitals

Managed Care Organizations

Physicians

Utilization Management

## Guideline Objective(s)

To evaluate the appropriateness of initial radiologic examinations for patients with diabetes suspected of having osteomyelitis

### **Target Population**

Patients with diabetes mellitus who are suspected to have osteomyelitis of the foot

### **Interventions and Practices Considered**

Diagnosis/Evaluation

- 1. X-ray
- 2. Magnetic resonance imaging (MRI) with and without contrast
- 3. Labeled leukocyte scan
- 4. Tc-99m 3-phase bone scan
- 5. Indium (In)-111 white blood cell (WBC) scan
- 6. Technetium (Tc)-99m sulfur colloid marrow scan
- 7. Ultrasound (US)
- 8. Computed tomography (CT) with and without contrast
- 9. Fluorine-18-2- fluoro-2-deoxy-D-glucose-positron emission tomography (FDG-PET)

# Major Outcomes Considered

Utility of radiologic examinations in differential diagnosis

# Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

- 1. Articles that have abstracts available and are concerned with humans.
- 2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 5 years unless the topic author provides other instructions.
- 3. May restrict the search to Adults only or Pediatrics only.
- 4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

#### Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

- Category 1 The conclusions of the study are valid and strongly supported by study design, analysis and results.
- Category 2 The conclusions of the study are likely valid, but study design does not permit certainty.
- Category 3 The conclusions of the study may be valid but the evidence supporting the conclusions is inconclusive or equivocal.
- Category 4 The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence for all articles included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an

appropriateness rating for each procedure listed in the table. Each individual panel member forms his/her own opinion based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

### Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

### Description of Methods Used to Formulate the Recommendations

Modified Delphi Technique

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distributes surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The ratings are a scale between 1 and 9, which is further divided into three categories: 1, 2, or 3 is defined as "usually not appropriate"; 4, 5, or 6 is defined as "may be appropriate"; and 7, 8, or 9 is defined as "usually appropriate." Each panel member assigns one rating for each procedure per survey round. The surveys are collected and the results are tabulated, de-identified and redistributed after each round. A maximum of three rounds are conducted. The modified Delphi technique enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive bias from fellow panelists in a simple, standardized and economical process.

Consensus among the panel members must be achieved to determine the final rating for each procedure. Consensus is defined as eighty percent (80%) agreement within a rating category. The final rating is determined by the median of all the ratings once consensus has been reached. Up to three rating rounds are conducted to achieve consensus.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is accepted as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

### Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Internal Peer Review

## Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

# Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

# Benefits/Harms of Implementing the Guideline Recommendations

### **Potential Benefits**

Selection of appropriate radiologic imaging procedures for evaluation and diagnosis of suspected osteomyelitis of the foot in patients with diabetes mellitus

### Potential Harms

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m²), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m². For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

# **Qualifying Statements**

## **Qualifying Statements**

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

# Implementation of the Guideline

## Description of Implementation Strategy

An implementation strategy was not provided.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

**IOM Domain** 

Effectiveness

# Identifying Information and Availability

### Bibliographic Source(s)

Kransdorf MJ, Weissman BN, Appel M, Bancroft LW, Bennett DL, Bruno MA, Fries IB, Hayes CW, Holly L, Jacobson JA, Luchs JS, Morrison WB, Mosher TJ, Murphey MD, Palestro CJ, Roberts CC, Rubin DA, Stoller DW, Tuite MJ, Ward RJ, Wise JN, Zoga AC, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® suspected osteomyelitis of the foot in patients with diabetes mellitus. [online publication]. Reston (VA): American College of Radiology (ACR); 2012. 8 p. [34 references]

### Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

1995 (revised 2012)

### Guideline Developer(s)

American College of Radiology - Medical Specialty Society

### Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

### Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Musculoskeletal Imaging

# Composition of Group That Authored the Guideline

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#### Financial Disclosures/Conflicts of Interest

Not stated

#### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Schweitzer ME, Daffiner RH, Weissman BN, Bennett DL, Blebea JS, Jacobson JA, Morrison WB, Resnik CS, Roberts CC, Rubin DA, Seeger LL, Taljanovic M, Wise JN, Payne WK, Expert Panel on Musculoskeletal Imaging. ACR Appropriateness Criteria® suspected osteomyelitis in patients with diabetes mellitus. [online publication]. Reston (VA): American College of Radiology (ACR); 2008. 7 p. [22 references]

### Guideline Availability

| Electronic copies: Available from the American College of Radiology (ACR) Web site  |  |
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Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

### Availability of Companion Documents

The following are available:

| • | ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable     |
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|   | Document Format (PDF) from the American College of Radiology (ACR) Web site  |
| • | ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 1 p. Electronic copies:          |
|   | Available in Portable Document Format (PDF) from the ACR Web site  |
| • | ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013       |
|   | Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site.   |
| • | ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2 p. Electronic     |
|   | copies: Available in Portable Document Format (PDF) from the ACR Web site  |
| • | ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 92 p. Electronic copies:          |
|   | Available in PDF from the ACR Web site   |
| • | ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 1 p. Electronic copies: Available in |
|   | PDF from the ACR Web site  |
| • | ACR Appropriateness Criteria® suspected osteomyelitis of the foot in patients with diabetes mellitus. Evidence table. Reston (VA):     |

| American College of Radiology; 2012. 17 p. Electronic copies: Available from the ACR Web site |  |
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#### **Patient Resources**

None available

#### NGC Status

This summary was completed by ECRI on May 6, 2001. The information was verified by the guideline developer as of June 29, 2001. This summary was updated by ECRI Institute on June 15, 2009. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This NGC summary was completed by ECRI Institute on September 7, 2012.

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